

**Amendments to the Drawings**

The attached sheet of drawings includes changes to Figure 8 adding reference numeral 443 for the inner balloon and reference numeral 445 for the outer balloon.

Attachment: Replacement Sheet

### **Remarks/Argument**

Applicant have received and carefully reviewed the Final Office Action mailed on December 30, 2009, the Advisory Action mailed on June 29, 2010, and the Notice of Panel Decision from Pre-Appeal Brief Review mailed July 13, 2010. Claims 43, 44, 46, 49, and 52 have been rejected. With this Amendment, claim 43 has been amended and new claim 64 has been added. As such, claims 43, 44, 46, 49, 52, 55, and 57-64 remain pending, of which claims 55 and 57-63 have been previously withdrawn from consideration. Favorable consideration of the following remarks is respectfully requested.

### ***Drawings***

On page 2 of the Final Office Action, the drawings were objected to as failing to comply with 37 C.F.R. 1.84(p)(5) because “they do not include reference sign(s) for the first and second balloon nor are there reference signs or numbers for these elements in the Specification”. While Applicants respectfully disagree, Applicants have amended the specification to recite “an inner balloon 443 defining an inner cooling chamber 444 and an outer balloon defining 445 an outer cooling chamber 446” and amended the drawings to include reference numeral 443 for the inner balloon and reference numeral 445 for the outer balloon. Withdrawal of the objection is respectfully requested.

### ***Claim Rejections - 35 U.S.C. § 103***

On pages 2-3 of the Final Office Action, claims 43, 44, 46, and 49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Wittenberger et al. (U.S. Patent No. 6,575,933) in view of Hammack et al. (U.S. Patent No. 6,679,906). Applicant respectfully traverses the rejection.

Turning to claim 43, which recites:

43. (Currently Amended) A device for minimally invasive medical treatment in a body of a patient, comprising:
- a tubular member having a proximal end and a distal end;
  - a cryo therapy apparatus connected to the distal end of the tubular member, wherein the cryo therapy apparatus comprises a first balloon and a second balloon, the first and second balloons arranged to define an inner chamber

and an outer chamber, at least a portion of the inner chamber being interior of the first balloon and at least a portion of the outer chamber being interior of the second balloon and exterior of the first balloon, a surface of the first balloon configured to retain a coolant within the inner chamber and a surface of the second balloon configured to retain the coolant within the cryo therapy apparatus if the first balloon fails; and

an optical sensor disposed within the cryo therapy apparatus for ~~[[to]]~~ monitoring temperatures created by use of the cryo therapy apparatus from within the cryo therapy apparatus, the optical sensor coupled to a retractable member capable of moving independently of the cryo therapy apparatus;

wherein the cryo therapy apparatus is sized and arranged for vascular introduction.

Without conceding the correctness of the rejection, Applicants have amended claim 43 to recite “an optical sensor disposed within the cryo therapy apparatus for monitoring temperatures created by use of the cryo therapy apparatus from within the cryo therapy apparatus, the optical sensor coupled to a retractable member capable of moving independently of the cryo therapy apparatus”. Nowhere does Wittenberger et al. or Hammack et al., taken either alone or in combination, appear to disclose at least this feature of claim 43.

In the Final Office Action, the Examiner appears to indicate that Wittenberger et al. fails to disclose the claimed optical sensor, but turns to Hammack et al. for support. Specifically, the Examiner cites to Figure 1-5 and column 34-51 of Hammack et al., which recites:

A temperature probe 20 is included and is movable within temperature probe lumen 15. As can be seen in FIGS. 3b, 4, 5 and 6, the temperature probe preferably includes temperature sensor such as a thermistor 21 at its distal end portion 22. Other temperature sensors may be employed, for example a thermocouple, light probes capable of sensing temperature, infra red sensors, or similar devices, as long as the sensor is able to sense the temperature of a specified tissue and generate a signal representing that temperature that may subsequently be transmitted to a controller for controlling the heat exchange of a heat exchange catheter or for some other desired purpose. In the example as shown in this embodiment, the temperature sensor is a thermistor, the temperature sensed is that of the blood surrounding the thermistor, and the signal generated is an electrical signal representing that temperature. Thermistors have been found to be advantageous because they can be made very small and because they can be made sufficiently accurate.

However, nowhere does the cited passage or Figures 1-5 of Hammack et al. appear to teach, suggest, or disclose the optical sensor disposed within the cryo therapy apparatus for monitoring temperatures created by use of the cryo therapy apparatus from within the cryo therapy apparatus, as recited amended claim 43. For at least these reasons, claim 43 is believed to be patentable over Wittenberger et al. in view of Hammack et al. For similar and other reasons, claims 44, 46, and 49, which depend from claim 43 and include additional distinguishing features, are also believed to be patentable over Wittenberger et al. in view of Hammack et al. Withdrawal of the rejection is respectfully requested.

On page 4 of the Final Office Action, claim 52 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Wittenberger et al. in view of LePivert (U.S. Patent No. 6,551,309). Applicant respectfully traverses the rejection.

Claim 52 recites:

52. (Previously Presented) A device for minimally invasive medical treatment in a body of a patient, comprising:  
a tubular member having a proximal end and a distal end;  
a cryo therapy apparatus connected to the distal end of the tubular member and comprising a first balloon and a second balloon, the first and second balloons arranged to define an inner chamber and an outer chamber, at least a portion of the inner chamber being interior of the first balloon and at least a portion of the outer chamber being interior of the second balloon and exterior of the first balloon, a surface of the first balloon configured to retain a coolant within the inner chamber and a surface of the second balloon configured to retain the coolant within the cryo therapy apparatus if the first balloon fails and prevent loss of the coolant to the body of the patient; and  
an optical imaging apparatus near the distal end of the tubular member to monitor temperatures resulting from use of the cryo therapy apparatus, wherein the cryo therapy apparatus is sized and arranged for vascular introduction.

Nothing in Wittenberger et al. or LePivert et al., taken either alone or in combination, appear to disclose many elements of claim 52, including for example, "a cryo therapy apparatus connected to the distal end of the tubular member and comprising a first balloon and a second balloon, the first and second balloons arranged to define an inner chamber and an outer chamber, at least a portion of the inner chamber being interior of the first balloon and at least a portion of the outer chamber being interior of the second balloon and exterior of the first

balloon, a surface of the first balloon configured to retain a coolant within the inner chamber and a surface of the second balloon configured to retain the coolant within the cryo therapy apparatus if the first balloon fails and prevent loss of the coolant to the body of the patient” or “an optical imaging apparatus near the distal end of the tubular member to monitor temperatures resulting from use of the cryo therapy apparatus”.

In the Final Office Action, the Examiner appears to indicate that Wittenberger et al. fails to specifically disclose an optical imaging apparatus near the distal end of the tubular member to monitor temperatures resulting from use of the cryo therapy apparatus, but turns to LePivert for support. Applicants respectfully disagree. In particular, the Examiner cited to column 10, lines 34-51 of LePivert, which recites:

In the one probe technique, the same probe fulfills the two requirements of hardening a thin layer of the tissue then treating it without moving the tip from its position. An embodiment of this technique consists in introducing a catheter 36, shown in FIG. 13, at the desired location through direct or imaging guidance, inserting the probe tip 15 into the catheter, introducing refrigerant into the probe while it remains within the bore of the catheter to initially freeze the tissue while the catheter wall prevents the liquid/gas mixture from escaping. The catheter is then withdrawn, as in FIG. 13, a few millimeters or centimeters to let the gas/liquid mixture flow freely in contact with the tissue. The catheter inner diameter and the material are calculated to adapt to the tip size and to be moved smoothly when it is deemed necessary for the probe application. This technique allows shaping of the ice ball according to the numbers and location of openings exposed by the controlled withdrawal of external catheter.

As can be seen, nothing in the cited passage of LePivert appears to disclose an optical imaging apparatus. Further, nowhere does LePivert appear to even recite the term “optical”. As such, Applicants respectfully submit that LePivert cannot be considered as disclosing “an optical imaging apparatus near the distal end of the tubular member to monitor temperatures resulting from use of the cryo therapy apparatus”, as recited in claim 52. For at least these reasons, claim 52 is believed to be patentable over Wittenberger et al. in view of LePivert. Withdrawal of the rejection are respectfully requested.

***Newly Presented Claims***

With this Amendment, Applicants have added newly presented claim 64. For similar reasons discussed above, as well as others, claim 64, which depends from claim 52 and includes additional distinguishing features, is believed to be patentable over the cited references.

***Conclusion***

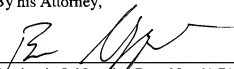
In view of the foregoing, all pending claims are believed to be in a condition for allowance. Further examination and withdrawal of the rejections is respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,  
DANIEL M LAFONTAINE

By his Attorney,

Date: \_\_\_\_\_

9/27/10

  
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